MATERIALS FOR DISCUSSION AT THE MAY 14 PUBLIC MEETING OF THE RISK ASSESSMENT ADVISORY CORE COMMITTEE

DISCUSSION OF DRAFT PLANS OF CAL/EPA'S BOARDS, DEPARTMENTS AND OFFICES TO IMPLEMENT THE RECOMMENDATIONS OF THE COMMITTEE'S REPORT

The following materials will be discussed at the May 14, 1997 public meeting of the Risk Assessment Advisory Core Committee. The meeting will be held at room 500 of the Library and Courts Building, 914 Capitol Mall, Sacramento and will begin at 9:30 a.m.

The materials provided include:

1. Meeting agenda
2. Draft implementation plans from:
    - The Office of Environmental Health Hazard Assessment
    - Department of Toxic Substances Control
    - State Water Resources Control Board/Regional Water Quality Control Boards
    - Department of Pesticide Regulation
    - California Air Resources Board
    - California Integrated Waste Management Board
3. Additional materials
    - Charter of the Risk Assessment Coordination Work Group, (RACWG), an inter-departmental group of staff scientists
    - Description of RACWG Fate and Transport Subcommittee
    - Draft Risk Characterization Policy: Guidance for Implementation (RACWG)

After completing a year-long review of Cal/EPA's risk assessment practices, the Risk Assessment Advisory Committee issued its report in October 1996 of findings and recommendations for improvements to Cal/EPA's risk assessment activities. In December 1996, Governor Pete Wilson signed Executive Order W-137-96 which requires the Boards, Departments and Offices of Cal/EPA to evaluate the report and to develop plans to implement the Committee's recommendations, as part of their strategic planning efforts for the next fiscal year.

The purpose of the meeting is (1) to provide a forum at which the Boards, Departments and Offices of Cal/EPA can present their draft plans to the Committee and the public and (2) to provide a mechanism to obtain feedback from the Committee and interested parties on these draft plans.

We strongly encourage you to come to the meeting and participate in the discussion of the draft implementation plans. Or, if you prefer, you may forward written comments to Dr. Thomas A. McDonald (address below) who will direct them to the appropriate department. Please submit comments by May 28, 1997.

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Office of Environmental Health Hazard Assessment
California Environmental Protection Agency

MEETING OF THE RISK ASSESSMENT ADVISORY COMMITTEE

DISCUSSION OF DRAFT PLANS OF CAL/EPA'S BOARDS, DEPARTMENTS AND OFFICES TO IMPLEMENT THE RECOMMENDATIONS OF THE COMMITTEE'S REPORT

May 14, 1997
Room 500, Library and Courts Building, 914 Capitol Mall, Sacramento

In accordance with the passage of Senate Bill 1082 (Calderon) of 1993, the Committee completed a comprehensive, external peer review of the risk assessment practices used by Cal/EPA, and issued its final report in October 1996. The report, entitled A Review of the California Environmental Protection Agency's Risk Assessment Practices, Policies, and Guidelines, describes the Committee's findings and recommendations for improvements to Cal/EPA's risk assessment activities.

In December 1996, Governor Pete Wilson signed Executive Order W-137-96 which, in part, requires the Boards, Departments and Offices of Cal/EPA to evaluate the report and as part of their strategic planning efforts, to develop plans to implement the applicable recommendations of the Committee's report.

The purpose of this meeting is two-fold: (1) to provide a forum at which the Boards, Departments and Offices of Cal/EPA can present their draft plans to the Committee and the public and (2) to provide a mechanism to obtain feedback from the core Committee and interested parties on these draft plans.

Meeting Chair: *Richard A. Becker, Director, OEHHA*

9:30 a.m. **Welcome and Introduction**
Richard A. Becker, Director, OEHHA

10:00 a.m. **Presentations of Draft Implementation Plans**

OEHHA's Draft Implementation Plan
Richard A. Becker, Director, OEHHA)

Committee and public comment and discussion

Department of Toxic Substances Control's (DTSC) Draft Implementation Plan
Steve M. DiZio, Senior Toxicologist, Office of Scientific Affairs, DTSC, Cal/EPA

Committee and public comment and discussion

12:00 a.m. **LUNCH**

1:30 p.m. **Presentations of Draft Implementation Plans (continued)**

State Water Resources Control Board (SWRCB)/Regional Water Quality Control Board's Draft Implementation Plan
Syed M. Ali, Staff Toxicologist, Chief of Planning Section, Division of Water Quality, SWRCB, Cal/EPA

Committee and public comment and discussion

Department of Pesticide Regulation's (DPR) Draft Implementation Plan
Jay P. Schreider, Principal State Toxicologist, Medical Toxicology Branch, DPR, Cal/EPA

Committee and public comment and discussion

3:00 p.m. **BREAK**

3:15 p.m. **Presentations of Draft Implementation Plans (continued)**

California Air Resources Board's (ARB) Draft Implementation Plan
Donald J. Ames, Asssistant Chief, Stationary Source Division, ARB, Cal/EPA

Committee and public comment and discussion

4:00 p.m. **Committee Summary and Recommendations**

5:00 p.m. **Meeting Adjournment**

DRAFT
(for discussion purposes only)

Office of Environmental Health Hazard Assessment
Implementation Plan for Addressing the Recommendations of the Risk Assessment Advisory Committee

Activity Description	Performance Measures
Consistency and Harmonization	
Implement Executive Order W-137-96 of the Governor and assist the Secretary of Environmental Protection to harmonize and improve risk assessment practices in the state of California.	Facilitate agencies and departments in preparing their workplans that address recommendations of the Risk Assessment Advisory Committee. Assist the Secretary of Cal/EPA to prepare a progress report to the Governor on the implementation of Executive Order W-137-96. Prepare a progress report to the secretary of Cal/EPA on the implementation of Executive Order W-137-96 by the Boards, Office and Departments of Cal/EPA.
Coordinate activities of the Risk Assessment Coordination Work Group (RACWG) to promote consistency in risk assessment practice within Cal/EPA. Form a subcommittee to address issues in fate and transport modeling.	Evaluate cancer and noncancer risk assessments with respect to harmonization and identify specific chemicals for reassessment based on greatest concern. Release lists of cancer potency factors and toxicity values that are to be used by all programs of Cal/EPA. Adopt with modifications the US EPA Guidance for Risk Characterization for use by all Cal/EPA Boards, Departments and Offices.
Harmonize risk assessment activities with US EPA offices in Washington DC and Region IX	Sign a Memo of Understanding with US EPA National Center for Environmental Assessment on collaboration on risk assessment activities. Develop FY 96-97 and FY 97-98 workplans with the center and with US EPA Region IX. Develop a screening level risk assessment method applicable across Cal/EPA programs, US EPA Region IX, RCRA and Superfund. Harmonize potency estimates for PCBs and adopt the I-TEF approach for assessing health risks associated with dioxin-like compounds across all programs of Cal/EPA.

Best Use of Scientific Information and Development of Guidelines	
Develop and coordinate technical support on guidance documents, policy documents, and white papers	Finalize Stochastic Exposure Assessment Guideline. Release a new guideline for the "Air Toxics Hot Spots" program Develop an unified multi-media, multi-pathway exposure assessment method that is acceptable to all Cal/EPA programs. Prepare a briefing book to the Secretary on identifying future emerging environmental challenges. Prepare white papers on scientific issues, e.g., criteria for generally accepted scientific principles and experimental protocols related to toxicity tests. Issue a report that summarizes the pilot study results and recommendations of an inter-departmental work group on the implementation of the draft US EPA Guidelines for Carcinogen Risk Assessment. Prepare supplemental guidance documents to be used together with the draft US EPA Guidelines for Carcinogens Risk Assessment.
Through the RACWG, develop a system of prioritizing chemical risk assessments, including revising and updating older risk assessments in light of new knowledge, so that we apply our resources where they will add the greatest value.	Develop a system for identifying chemical risk assessments for re-evaluation or revision New risk assessments using updated methods or toxicity data.
Continue staff training and professional development activities	Attend and make contributions to professional society and scientific meetings/forums. Actively participate in state and national coordinating and harmonization committee meetings, on risk assessment issues. Coordinate calendar of an agency-wide technical training series.
Continue ongoing efforts in methods development. e.g., physiologically-based pharmacokinetics, stochastic methods, benchmark dose, and molecular mechanisms of carcinogenesis (including receptor mechanisms).	Publish scientific papers in peer reviewed journals. Team up with UC to organize workshops on new techniques or approaches in human health risk assessment, e.g., benchmark dose for cancer and non-cancer endpoints. Apply new scientific methods to Public Health Goals, Proposition 65 and the Air Toxic Contaminants programs.

Peer Review and Peer Involvement	
Convene and provide technical and logistical support to the Core members of the RAAC to advise Cal/EPA on implementation of the RAAC recommendations	Hold 1-2 public meetings, coordinate the preparation of briefing materials.
Assist Boards, Departments and Offices in developing and implementing scientific peer review processes.	
Continue or expand ongoing peer review and public outreach activities.	Develop Standard Operating Procedures for internal and external peer review.
Interface Between Risk Assessment and Risk Management	
Organize training courses for risk assessors and risk managers on risk assessment and risk communication.	Partner with US EPA Region IX in providing training courses to state and local government staff in Risk and Decision Making and Risk Communication and Public Involvement.
Communicate with and educate stakeholders by means of seminars, articles in popular and business press, computer networks on issues related to environmental pollution and public health.	Provide educational materials and presentations on human health risk assessment to staff of other Boards and Departments of Cal/EPA, legislators, local governments, and the public. Develop and write a layman's guide to risk assessment. Post updates on the department's activities on the OEHHA world wide web site.
Organization and Resources	
Develop and implement proactive partnerships with other state departments and private industry for problem-solving and to ensure environmental protection.	Sign inter-departmental agreement with Department of Health Services on increasing collaboration and sharing of expertise. Complete Memo of Understanding with Department of Pesticide Regulation on roles, responsibilities, project planning and tracking.

Narrative Descriptions of Implementation Activities and Performance Measures

Consistency and Harmonization:

Implement Executive Order W-137-96 of the Governor

OEHHA has been designated by the Executive Order as the lead agency for coordinating a state-wide effort to improve the quality and consistency of risk assessment practices in California through the implementation of the recommendations of the Risk Assessment Advisory Committee. The Executive Order also required the Secretary of Cal/EPA to convene a task force of agencies and departments outside Cal/EPA to evaluate and implement the recommendations of the RAAC. OEHHA will provide technical assistance to the members of the task force and help them to evaluate the recommendations of the RAAC and prepare implementation plans that address the recommendations.

In addition, OEHHA is also working with other Boards and Departments of Cal/EPA to facilitate their preparation of draft implementation plans that address RAAC recommendations as part of their strategic plan for the fiscal year 1997-1998. OEHHA will hold a public meeting in late spring of 1997 for the core members of the RAAC to review and provide inputs on the draft implementation plans of the Boards and Departments of Cal/EPA.

Performance measures of this activity include: (1) minutes from the public meeting of the core members of the RAAC to provide advice on Cal/EPA implementation plans, (2) assist the Secretary in preparing a progress report to the Governor on the implementation of Executive Order W-137-96, resulting from the task force activities, (3) a progress report to the Secretary of Cal/EPA on the implementation of Executive Order W-137-96 by the Boards, Office and Departments of Cal/EPA, and (4) improved overall scientific quality and consistency of application of chemical risk assessment in California state agencies.

Cal/EPA Risk Assessment Coordination Work Group (RACWG)

OEHHA chairs the Cal/EPA Risk Assessment Coordination Work Group (RACWG), which has been formally established within Cal/EPA. Comprised of technical representatives from each of the boards, departments and offices, this Cal/EPA Risk Assessment Coordination Work Group replaces the long-standing, informal Standards and Criteria Work Group. Consistent with the RAAC recommendations, the mission/objective of this group is to provide advice on toxicology and human health and ecological risk assessment issues to the executive officers and directors of boards and departments within Cal/EPA, and to the Secretary for Environmental Protection. Through its activities, the Cal/EPA-RACWG aims to ensure that risk assessments which are used as the basis for risk management decisions reflect the best available science, and

risk assessment practices and methods are consistent throughout the Agency. To the extent appropriate, the Cal/EPA -RACWG will also attempt to harmonize Cal/EPA's risk assessment practices with those of the US Environmental Protection Agency. Recently, Cal/EPA-RACWG drafted a risk characterization policy based on the US EPA Risk Characterization Guidelines (1995). The policy is currently undergoing review for adoption by all Cal/EPA Boards & Departments. The Cal/EPA-RACWG strives to achieve consensus among Cal/EPA scientists on issues relating to toxicology and risk assessment. By providing an opportunity for scientists to meet, identify, discuss, debate and coordinate scientific issues and activities, the Cal/EPA-RACWG seeks to ensure that science policy decisions and risk assessment criteria, guidance, and policies used for regulatory decision-making are based on a firm foundation of science.

Performance measures of this activity include: (1) publishing and circulating meeting minutes, (2) update and distribute (via OEHHA web site and other media) consensus Cal/EPA Cancer Potency Factor list, and (3) improved intra-agency consistency in risk assessment practice through the evaluation and implementation of the technical recommendations of the RAAC.

<u>Harmonize risk assessment activities with US EPA offices in Washington DC and Region IX</u>

1. *Develop a memorandum of understanding (MOU) with US EPA National Center for Environmental Assessment.*

OEHHA has recently signed a memorandum of understanding with its counterpart at the US EPA, the National Center for Environmental Assessment (NCEA). OEHHA and NCEA will work to foster harmonization of the State and federal risk assessment programs to reduce the potential for conflicting approaches and methods, to exchange work products, and to share resources more efficiently. This promises also to ensure close cooperation and collaboration between Cal/EPA and US EPA in other activities, including conducting new chemical-specific risk assessments, application of new scientific advances in risk assessment and implementation of the much anticipated, revised US EPA cancer guidelines.

Performance measures for this effort will include (1) a signed MOU between OEHHA and NCEA, (2) the development of inter-agency workplans for the FY 96-97 and FY 97-98, and (3) successful work products.

2. *Develop a screening level risk assessment method for use by Cal/EPA and US EPA Region IX*

Cal/EPA and US EPA Region IX have begun a collaborative effort to develop a screening-level approach for assessing risk posed by chemicals as part of RCRA and Superfund programs. This method would be acceptable to both state and federal agencies for sites or hazards assessed in California, thereby, streamlining the overall regulatory processes. Possible approaches are being evaluated. For example, one approach would

be to develop a "look-up" table of remedial values for different media that use the most conservative endpoint (e.g., cancer, ecological, reproductive) to screen for potential of hazard. Activities include periodic meetings and coordination of resources to develop the method.

Performance measures include: (1) a working screening level risk assessment method for use in the RCRA and Superfund programs, (2) increased state and federal harmonization, and a overall streamlined regulatory processes.

3. *Harmonize the dose-response evaluations of PCBs and dioxin-like chemicals within Cal/EPA and US EPA.*

US EPA regulates 2,3,7,8-TCDD and other dioxin-like compounds using an approach based on the relative toxicity of these compounds to that of 2,3,7,8-TCDD. This approach is called the Toxicity Equivalent Factor (TEF) approach. Slight differences exist between the TEFs used by Cal/EPA and those developed by the World Health Organization (designated I-TEF for International-TEF). OEHHA will take the lead in ensuring consistent potency factors and approaches are used across all programs and media.

In 1996, US EPA released its revised cancer potency values for polychlorinated biphenyls (PCBs). OEHHA is considering adopting the revised potency values for PCBs for consistent use throughout Cal/EPA.

The performance measure will be the adoption of the I-TEF approach for dioxin-like compounds, and the revised potency values for PCBs by Cal/EPA.

Use of Best Scientific Information

<u>Develop and coordinate technical support on guidance documents, policy documents, and white papers</u>

As stated in the RAAC report, guidelines can be used to promote quality and predictability, as well as improve consistency and administrative efficiency. A major undertaking has been the development of methods to better characterize variability and uncertainty in human exposure assessment. This project consists of the development and finalization of the Stochastic Exposure Assessment Guidelines as part of the Air Toxics "Hot Spots" program. OEHHA, in cooperation with other Cal/EPA departments and external scientific experts, has produced a first draft and submitted it for public comment. OEHHA will revise the guidelines in response to public comment and peer review. OEHHA, in conjunction of other boards and departments, is also in the process of reviewing and considering the adoption of the new US EPA Guideline on Risk Characterization and the draft US EPA Guidelines for Carcinogens Risk Assessment. OEHHA has formed a team of scientists to apply the draft US EPA cancer guidelines to 4

selected chemicals. The team will evaluate the approaches and methods described in the guidelines and identify areas where supplemental guidance or information is needed.

OEHHA is also coordinating an intra-agency effort to evaluate new scientific information for the purposes of identifying emerging environmental challenges. This project will attempt to try to predict environmental or public health problems (stemming from environmental exposures to chemicals) that will have a significant impact and the agency will need to act upon in the near future. Activities include literature searches and evaluations, internal working sessions and a set of public workshops.

Performance measures for these efforts will include: (1) finalization of the Stochastic Exposure Assessment Guidelines for the Air Toxics "Hot Spots" program, (2) the adoption of guidance on risk characterization based primarily on the 1995 US EPA Guideline on Risk Characterization, and (3) a report that summarizes the findings and recommendations of the team established to evaluate the draft US EPA Guidelines for Carcinogens Risk Assessment, (4) issue supplemental guidance documents, if warranted, to be used together with the draft US EPA Guidelines for Carcinogens Risk Assessment, and (5) a briefing book to the Secretary on identifying emerging environmental challenges for the future.

Through the RACWG, develop a system of prioritizing chemical risk assessments, including revising and updating older risk assessments in light of new knowledge, so that we apply our resources where they will add the greatest value.

OEHHA will work with technical staff of other Boards and Departments of Cal/EPA to develop a system for identifying chemical risk assessments that warrant re-evaluation or revision. The identification system will be based on a number of considerations, such as public health importance (e.g., magnitude and nature of hazard) and programmatic concerns (e.g., number of sites), availability of new toxicity information or assessment methods, and existence of significant difference between Cal/EPA and US EPA risk estimates.

Performance measure of this activity includes: (1) development of a system for identifying chemical risk assessments for re-evaluation or revision, (2) a schedule for the development of new risk assessments using updated methods or toxicity data, and (3) revised risk assessments.

Continue staff training and professional development

Risk assessment is an evolving discipline, new approaches are being proposed and new information are being provided by scientists on a continuing basis. OEHHA will continue to encourage staff to attend and make contributions to professional society and scientific meetings, forums and conferences. OEHHA will also support, within the confines of budget limitations, other forms of training including continual education and

professional development including publishing articles in the scientific literature. These activities will also include active participate in state and national coordinating and harmonization committee meetings on risk assessment issues. OEHHA will participate in organizing and coordinating a calendar of an agency-wide technical training series.

Performance will be measured by (1) the implementation of Individual Development Plans to include time budgeted for development of publications, attendance at conferences, educational training opportunities and cross training to enhance staff capabilities to achieve OEHHA's mission, (2) number of official positions held by OEHHA staff in professional societies, (3) overheads and handouts of the agency-wide technical training courses, and (4) satisfaction of attendees as gauged by responses on standard, state training request forms.

Continue ongoing efforts in methods development

OEHHA is also working to develop new methods and to apply new information and methods into risk assessment practice. In the area of dose-response assessment, new methods and approaches that are being evaluated include the use of biologically-based models, the use of the benchmark dose approach, the use of uncertainty factors in evaluating acute toxicity, and the evaluation of molecular mechanisms of carcinogenesis. OEHHA is developing methods to better characterize uncertainty and variability in human exposure assessment through the development and application of stochastic methods. As a matter of general practice, OEHHA will also look to partnering with university, industry and other scientific institutes to hold workshops to gain public and expert input on new techniques or approaches in risk assessment. OEHHA will consider developing guidance documents or white papers on these and other current issues.

Performance measures include: (1) published scientific papers in peer-reviewed journals, (2) minutes or reports stemming from any workshops on new methods, and (3) risk assessments (Public Health Goals, Proposition 65, and Air Toxic Contaminants) incorporating new scientific information, methods or techniques.

Peer Review and Peer Involvement

Scientific peer review was a consistent and clear theme stressed by the RAAC throughout its review. The RAAC noted that peer review was an excellent means of assuring high quality scientific products and processes, increasing credibility of the final product, and bringing new scientific methods and information into the risk assessment process. OEHHA's plans for activities related to scientific peer review included convening and providing technical and logistical support to the Core members of the RAAC to advise Cal/EPA on implementation of the RAAC recommendations. This is expected to entail holding 1-2 public meetings and coordinate the preparation of briefing materials. OEHHA plans to assist, where appropriate, the other Boards and Departments of Cal/EPA in developing and implementing processes for scientific peer involvement

and peer review. OEHHA will continue or expand its ongoing scientific peer involvement and peer review as well as public outreach activities. To help improve these activities, OEHHA will develop Standard Operating Procedures for internal and external scientific peer involvement and peer review.

Performance measures include (1) minutes or memoranda from meeting(s) of the Core members of the RAAC on Cal/EPA implementation plans, (2) the development of Standard Operations Procedures, and (3) improvements in the quality and credibility of risk assessments prepared by OEHHA.

Interface Between Risk Assessment and Risk Management

Organize training courses for risk assessors and risk managers on risk assessment and risk communication.

In response to the RAAC's recommendations to improve the interaction of risk assessors and risk managers, and to improve risk communication, Cal/EPA, with the assistance of US EPA Region IX, will provide a series of training courses. Two courses are currently underway, entitled (1) Risk Assessment and Decision Making and (2) Risk Communication and Public Involvement. The courses are being offered this spring and will be initially targeted for risk managers within the Cal/EPA Boards and Departments and other state and local regulatory agencies. Similar training courses will be modified for local and regional governmental staff and risk managers as needed. Specifically, OEHHA will develop a one-day course in risk assessment for local environmental health programs. OEHHA will coordinate this effort within Cal/EPA.

Performance measures will include the development of the training courses, including instructional materials. OEHHA and Region IX will set up a schedule and convene a series of courses for state and local governmental staff in Risk Assessment and Decision Making and Risk Communication and Public Involvement.

Communicate with and educate stakeholders by means of seminars, articles in popular and business press, computer networks on issues related to environmental pollution and public health.

The RAAC noted that communicating risk information to external stakeholders was an important and integral part of the risk assessment/risk management process. OEHHA plans to further its ongoing efforts in this area. OEHHA will continue its participation in trade shows and provide training sessions on risk assessment to layman and practitioners of the field.

The measures of this activities will include providing educational materials and making presentations on human health risk assessment to staff of other Boards and

Departments of Cal/EPA, legislators, local governments, and the public. In addition, OEHHA will develop and write a layman's guide to risk assessment which will attempt to make the risk assessment process more transparent to general audiences. OEHHA will also post updates on the department's activities and important documents on the OEHHA world wide web site.

Organization and Resources

Develop and implement proactive partnerships with other state departments and private industry for problem-solving and to ensure environmental protection.

The RAAC recommended that OEHHA and other departments of Cal/EPA assess whether the professional expertise of their staff is properly aligned with the needs of their programs. The Committee further recommended that a good means to obtain necessary expertise would be for the departments to enter into formal agreements with other agencies, universities, private industry or similar institution to gain the needed resources. Additional Committee recommendations called for Cal/EPA to seek out ways to streamline the risk assessment process.

The performance measures of this activity include: (1) signing inter-departmental agreements with other state agencies, such as Department of Health Services and Department of Pesticide Regulation, on increasing collaboration and sharing of expertise, and (2) establishing formal agreements or contracts with other non-governmental research and learning institutes on providing consultative services to OEHHA.

STRATEGY FOR IMPROVING THE SCIENCE AND APPLICATION OF RISK ASSESSMENT

SB 1082 RAAC IMPLEMENTATION WORK PLAN

Human and Ecological Risk Division
California Environmental Protection Agency
Department of Toxic Substances Control
Science, Pollution Prevention, and Technology Program

I. Harmonization and Consistency

A. Continue work within Cal/EPA to achieve consistency of risk assessment methods and the use of the best available science.

1. Work within the Cal/EPA *Risk Assessment Coordination Work Group* to develop DTSC guidance on the application of stochastic approaches to risk assessment process for hazardous waste sites and facilities.

2. Serve as lead for the Cal/EPA's *Environmental Fate and Transport Work Group*. Develop Cal/EPA wide inventory of expertise and resources focusing on fate and transport issues. Develop a proposed Cal/EPA-wide framework for interaction and mutual support to address barriers related to legal authority and special fund expenditure restrictions.

3. Continued to work within the Cal/EPA's OEHHA *Exposure Assessment and Stochastic Analysis Work Group* (in support of the OEHHA Air Toxics Hot Spots Program) so this guidance is relevant to developing DTSC Cal/TOX approach to stochastic estimates of risk .

4. Continue to work with the ARB technical staff to identify and integrate a mutually agreeable analytical dispersion model for contaminants in the air compartment into Cal/TOX.

5. Ask for support from WB technical staff to identify and integrate a mutually agreeable analytical saturated and saturated transport and dispersion model for contaminants in the subsurface and groundwater compartment into Cal/TOX.

B. Continue work with US EPA to achieve consistency of risk assessment methods and the use of the best available science.

1. Continue to support the U.S. EPA (Region 9)-Cal/EPA harmonization project on "Preliminary Soil Remediation Goals (PRGs)." Work for the integration of a full multimedia multi-pathway risk assessment approach into the process of estimating risk and calculating PRGs for (1) hazardous waste sites and (2) closure and corrective action at permitted facilities.

2. Continue to provide Cal/TOX outputs (input parameter varied) for exposure scenario-specific PRGs using the Cal/TOX to the "harmonization" workgroup consisting of Cal/EPA and US EPA (Region 9) staff.

3. Incorporate toxicological properties, chemical properties, exposure and fate/transport parameters, environmental compartment and media characteristics and probability distributions into a database for Cal/TOX that have been have been (1) developed by/for US EPA and various Cal/EPA agencies and (2) reported in the peer reviewed scientific literature.

4. Continue joint research with US EPA HQ, the University of California, Davis Risk Sciences Center, and Lawrence Berkeley Laboratory on the development of a plant uptake and distribution model for Cal/TOX.

5. Continue joint efforts with US EPA Region 9 and other State and Federal Agencies on the development of risk assessment guidelines and procedures for ecological risk assessment. Utilize the Federal IPA process to have staff develop "field investigation" experience for ecological risk assessment.

6. Continue joint research with US EPA HQ, UCD Risk Sciences Center, and LBL to modify Cal/TOX to estimate risks from heavy metals.

II. Peer Review

A. Continue a formalized program of internal and external scientific peer review.

1. DTSC Internal - Continue Senior Toxicologist peer review of Associate and Staff Toxicologist analysis of site and facility risk assessments submitted by responsible parties and permit applicants, respectively.

2. DTSC Internal - Continue additional peer review by project management staff of Associate and Staff Toxicologist analysis of site and facility risk assessments submitted by responsible parties and permit applicants, respectively for policy and procedural inconsistencies

3. External - Continue HERD peer review of OEHHA analysis of site and facility risk assessments for which DTSC has assigned OEHHA to be lead on a risk assessment under the interagency agreement.

4. Broaden external/internal peer review of Cal/TOX, that is in concert with the peer review policy of Cal/EPA.

III. Best Use of Scientific Information and Development of Guidelines.

A. Encourage and support scientific training and professional development.

1. Promote the use of the "Individual Development Plan" process to encourage and facilitate scientific staff efforts to publish scientific papers in peer reviewed journals.

2 . Continue the use of the DTSC "Individual Development Plan" process to encourage and facilitate participation of scientific staff in (1) continuing education and scientific societies and (2) state and national scientific forums.

3. At the start of the fiscal year planning phase, continue to ask for allocation of funds sufficient for continuing education, participation in scientific societies, and "Diplomate of the American Board of Toxicology" certification.

4. Continue to develop course material for exposure assessment, stochastic analysis and Cal/TOX training. Continue improvements in one quarter

upper division course for UC Davis Department of Environmental Toxicology. Continue improvements in 3-day course for UC Davis Extension. Continue improvements in 3-day course for Cal/EPA staff.

B. Document the procedures and assumptions used in the conduct of the stochastic multi-media, multi-pathway risk assessment using the best available science.

1. Complete the HERD guidance manual on the theory, background, and operation of the multi-media risk assessment program, Cal/TOX, to document behavior of Cal/TOX. Develop training course manual for Cal/TOX. Make material available on www site.

2. Continue to examine and update the structure, process and data embedded in Cal/TOX. Continue "sensitivity runs" on various input parameters to study behavior of Cal/TOX.

3. Continue the development of "abstracted" air dispersion models for the offsite fate and transport of chemicals in the air. Integrate these into Cal/TOX and write an associated chapter in Cal/TOX guidance.

4. Continue the development of "abstracted" groundwater transport and dispersion models for prediction of the offsite fate and transport of chemicals in unsaturated and saturated groundwater compartments. Integrate into Cal/TOX and write an associated chapter in Cal/TOX guidance.

5. Continue expansion of the toxicological properties, chemical properties, exposure and fate/transport parameters, environmental compartment and media characteristics and probability distributions database for Cal/TOX and associated chapters in Cal/TOX guidance.

6. Continue the development of guidance on the characterization of uncertainty and variability, both for the risk assessment process in general and specifically for Cal/TOX. Develop the process to ensure that the level of uncertainty is accurately characterized and appropriately portrayed.

7. Continue distribution of Cal/TOX through US National Technical Information Service and the DTSC Human and Ecological Risk Division world-wide-web site. Continue enhancement of the world-wide-web site for the distribution of Cal/TOX, associated documents, updates, advice and user-input. Continue expansion of links to the DTSC HERD world-wide-web site by other risk assessment/risk management involved sites.

IV. Interface Between Risk Assessment and Risk Management

A. Continue coordinated interaction between HERD scientists and DTSC Program risk managers.

1. Continue to meet with DTSC Program risk managers by attendance of monthly Division and Branch Level Meetings on HWCA, DSMOA, and RP-lead sites and projects to ensure (1) early consideration of the risk assessment process, resources, and limitations within the risk management process, (2) that the resources devoted to the risk assessment are commensurate with the significance of the risk management decision that is needed and (3) the risk assessment product is fully considered in the final risk management decision.

2. Continue training of DTSC Program risk managers on the fundamental concepts, process and outputs of risk assessment by HERD scientists at monthly DTSC Division and Branch Level Meetings on HWCA, DSMOA, and RP-lead sites and projects.

3. Continue scientific support of DTSC's Hazardous Waste Management "Regulatory Structure Update" in the development of risk-based regulatory classification of hazardous waste.

4. Continue scientific support of DTSC's Site Mitigation's Program's "Site Mitigation Update" in the development of acceptable risk ranges, risk-based remediation goals, and risk-based tiered approach to site-mitigation and cleanup.

5. Continue scientific support of DTSC's Office of Pollution Prevention and Technology Development "Tiered Certification Program" in the consideration of potential risks posed by a technology during routine operation, off-spec operation, catastrophic process failure, or transportation related accidents.

6. Continue to provide scientific support at public meetings whereby external stakeholders provide review and comment on a specific risk assessment.

STATE WATER RESOURCES CONTROL BOARD'S PLAN FOR IMPLEMENTING THE RECOMMENDATIONS OF THE SB 1082 RISK ASSESSMENT ADVISORY COMMITTEE

The State Water Resources Control Board (SWRCB) and its nine Regional Water Quality Control Boards (RWQCB) have primary responsibility for the coordination and control of water quality in California. As mandated by the Porter-Cologne Water Quality Control Act of 1969, the SWRCB implements a number of water quality control programs to protect the beneficial uses of surface and ground waters of the State. In implementing this State law as well as the federal Clean Water Act, the SWRCB develops ambient water quality standards to protect human health as well as the health of aquatic life.

The SWRCB and the RWQCBs are mainly risk management agencies. Nevertheless, we are directly or indirectly involved in all phases of ecological and human risk assessment activities. The SWRCB's Division of Water Quality is primarily involved in risk assessment activities dealing with surface water, whereas the Division of Clean Water Programs is primarily involved in risk assessment activities dealing with ground water and land disposal programs. The RWQCBs implement both surface and ground water programs (Attachment 1). The SWRCB and the RWQCBs do not conduct any research involving human health dose-response relationships. We rely primarily on other state and federal agencies [such as Cal/EPA's Office of Environmental Health Hazard Assessment (OEHHA) and the U.S. Environmental Protection Agency (U.S. EPA)] for this information which we review and evaluate particularly during the development and adoption of ambient water quality standards.

The SWRCB and the RWQCBs are conducting ongoing strategic planning efforts to establish multi-year, organization-wide directions and priorities. The SWRCB Strategic Plan was adopted in June 1995. It is being revised to include implementation of the Risk Assessment Advisory Committee's (RAAC) recommendations pursuant to Governor Wilson's Executive Order # W-137-96 of December 10, 1996 (Attachment 2).

The SWRCB's draft action plan for implementation of five major categories of RAAC recommendations is summarized in Attachment 3, and is briefly discussed below.

I. Consistency and Harmonization

The SWRCB and all the nine RWQCBs will work to achieve consistency on issues such as designation of beneficial uses of water bodies, procedure for development of site-specific water quality objectives, and ground water cleanup levels. While working to achieve statewide consistency, RWQCBs will use their discretion to consider regional conditions when conducting human and ecological risk assessment activities leading to site-specific risk management decisions.

The SWRCB and RWQCBs will continue to work within Cal/EPA to achieve consistency of risk assessment methods and the use of the best available science through participation in:

- Cal/EPA's RAAC Policy Work Group to develop an agency-wide implementation plan for RAAC's recommendations, and monitor the progress on the implementation of the performance measures.

- Cal/EPA's Risk Assessment Coordination Work Group (RACWG) of technical representatives of the Agency's boards, offices, and departments (BODs). This Work Group, chaired by OEHHA, provides advice on toxicology and human health and ecological risk assessment issues to the BODs. The mission of RACWG is to ensure that the BODs risk management decisions are based on scientifically defensible and internally consistent risk assessment practices and methods.

- Cal/EPA's Environmental Fate and Transport Work Group to assimilate and disseminate information on environmental fate and transport data bases, models, and expertise at SWRCB and RWQCBs for Cal/EPA's inventory report being drafted by the Work Group with the Department of Toxic Substances Control as the lead.

- Cal/EPA's Biological Technical Advisory Group for ecological risk assessment at military facilities and superfund sites.

- OEHHA's Ecotoxicology Inter-Agency Work Group to develop internally consistent guidelines based on the best available science for the ecotoxicological risk assessments.

The SWRCB and RWQCBs will continue to work with U.S. EPA to achieve consistency of risk assessment and the use of the best available science through:

- Participation in the Cal/EPA-U.S. EPA (Region 9) Risk Harmonization Interagency Work Group which is evaluating the existing state and federal human health risk assessment paradigms (such as Risk Based Cleanup Actions, and Preliminary Soil Remediation Goals). This effort has been undertaken in order to increase consistency in how human health risk assessments are conducted and evaluated in California. The current focus is to develop an approach to assess soil contaminated sites using a tiered approach which incorporates the use of screening level tables at the initial tier and progressive use of site-specific data at subsequent tiers leading to a site-specific risk assessment.

- Coordination with U.S. EPA (Region 9) in developing the two statewide water quality control plans -- Inland Surface Waters Plan (ISWP), and Enclosed Bays and Estuaries Plan (EBEP). The two phase approach involves developing a policy in Phase 1 that includes implementation provisions for the

federal water quality criteria to be promulgated by U.S. EPA (Region 9) via the California Toxic Rule. Phase 2 will build up on Phase 1 products to develop full water quality control plans that include State-adopted objectives and a program for their implementation. The Phase 1 implementation policy will be used by SWRCB and RWQCBs to implement the federal criteria until the SWRCB adopts the ISWP/EBEP. The policy, with appropriate modifications, will become the program of implementation for the ISWP/EBEP in Phase 2. The Phase 1 schedule calls for the release of a draft policy and Functional Equivalent Document (FED) for public review by August 1997, a public hearing in the fall of 1997, and adoption by the SWRCB in the spring of 1998. An additional 12-18 months will be needed to complete Phase 2.

II. Best Use of Scientific Information and Development of Guidelines

The SWRCB and RWQCBs will continue to use the best scientific information and water quality data in risk assessment and management practices. Some of the implementation measures include:

- Keeping staff updated on recent scientific developments through training, subscription to scientific journals, and participation in the scientific conferences and workshops.

- Inviting scientific experts to the State Board workshops and meetings for presentations of informational items of current interest.

- Conducting the scientific peer review process as outlined Section III below.

The following measures will be taken in the area of water quality data base management:

- Develop proposal for Comprehensive Water Quality Data Management Project to collect, validate, and disseminate water quality data. Review statewide water quality data collection and management practices for overlap, institute quality control measures, and improve accessibility of present data.

- Continue the SWRCB Information Management Team's ongoing efforts to improve data accessibility.

- Continue to maintain and improve the quality control measures of the U.S. EPA's STORET (Storage and Retrieval) water quality data base, and make it available to interested parties.

- Continue to provide SWRCB and RWQCB information on ground water contamination with pesticides to the Department of Pesticide Regulation for the annual report to the Legislature.

- Continue to participate and provide input into Cal/EPA's Environmental Indicators Report.

- Coordinate with other agencies in data collection and management activities, such as Department of Water Resources' California Environmental Resource Evaluation System (CERES), Land Use Planning Information Network (LUPIN), and Watershed Information Technical System (WITS) data bases.

- Provide on electronic bulletin board and web site SWRCB's water quality monitoring data from State Mussel Watch Program, Toxic Substances Monitoring Program, and Aquatic Toxicity Program, and sediment quality data from the Bay Protection and Toxic Cleanup Program.

The SWRCB and RWQCBs staff will participate in the development of risk assessment guidelines (e.g., Cal/EPA's development of guidance for communicating the basis for "science based" policy decisions). These guidance documents are intended to provide the scientific and policy basis for default options (such as cleanup to background levels), and uncertainty/safety factors for extrapolating laboratory toxicity data with test animals to humans, including sensitive populations such as children and old people with immune deficiency.

III. Peer Review and Peer Involvement

The SWRCB will continue to implement the peer review and peer involvement program adopted by the Board in March 1996. The SWRCB and RWQCBs Science Advisory Committee consists of several ad hoc subcommittees, including the (1) Marine Bioassay Project Scientific Review Committee, (2) Microbiological Advisory Committee, (3) Marine Toxicity Committee, and (4) Bay Protection and Toxic Cleanup Program's (BPTCP) Scientific Planning and Review Committee. New scientific peer review committees will be formed when needed. This approach has been an efficient way of receiving impartial scientific advisory services in a timely manner considering the complexity of water quality issues faced by the SWRCB and the nine RWQCBs.

The SWRCB will continue the internal Cal/EPA scientific review process by sharing draft risk assessment and management documents with the BOD scientists to solicit their review comments. Further, these draft documents will also be shared with other pertinent State agencies such as the Department of Health Services (DHS) and the Department of Fish and Game.

IV. Interface between Risk Assessment and Risk Management

The SWRCB will continue to seek early input from risk managers, external stakeholders and general public during the risk assessment process. Staff will continue the external stakeholder involvement through existing and ad hoc committees such as the Nonpoint Source Committee, ISWP and EBEP Task Forces, and the BPTCP's Advisory Committee. The SWRCB has also

convened a stakeholder group consisting of the regulated community, environmental groups, and local and State agencies to provide input on proposed revisions to regulations concerning discharges of waste to land.

Cross training will be provided to SWRCB risk assessors and risk managers to enhance early communication involving risk assessment and risk management decisions. Although risk assessment is a well defined scientific process while risk management is based on socio-economic factors and best professional judgement concerning feasible treatment technologies, SWRCB and RWQCBs will foster positive interactions of risk assessors and risk managers.

SWRCB will identify program areas that would benefit from the translation of emerging risk assessment methods into risk management policies (e.g., pollution prevention practices such as double lined underground fuel storage tanks for replacement of leaking tanks). SWRCB and RWQCBs will participate in Cal/EPA's Emerging Environmental Challenges Program to provide management with early warning of future water quality problems which may potentially impact human health and the environment.

V. Organization and Resources

The SWRCB and RWQCBs will continue to balance the level of effort and resources with the importance and extent of a particular risk to humans and environment. The SWRCB's tiered approach for characterizing nature and extent of ground water pollution incorporates a balancing of effort and resources in ground water cleanups through an evaluation of technological considerations and economic feasibility.

SWRCB lacks adequate resources for various scientific disciplines required for risk assessment process, particularly in the areas of contaminant fate and transport, environmental chemistry, and modeling. Therefore, we are dependent upon other organizations (e.g., OEHHA, DHS) to fulfill some of our risk assessment needs. Any increase in our present responsibilities would require an augmentation of our capabilities. The SWRCB Strategic Plan's training program will continue to provide staff with training in the scientific fields of environmental fate and transport of toxicants, statistics, modeling, hazard identification, exposure assessment, toxicological dose-response relationships, risk characterization, and other pertinent areas of risk assessment. Staff will be encouraged to join scientific professional organizations such as the Society of Environmental Toxicology and Chemistry, attend national and international scientific conferences and workshops, present platform or poster papers, and publish papers in peer-reviewed journals.

STATE WATER RESOURCES CONTROL BOARD (SWRCB) AND REGIONAL WATER QUALITY CONTROL BOARDS (RWQCB) RISK ASSESSMENT/RISK MANAGEMENT ACTIVITIES[1]

ACTIVITY	HUMAN HEALTH			ECOLOGICAL HEALTH		
	DWQ[2]	DCWP[3]	RWQCB	DWQ	DCWP	RWQCB[2]
RISK ASSESSMENT						
Hazard Identification	O	X[4]	X[4]	X[5]	O	X[5]
Exposure Assessment	X[5]	X[6]	X[6]	X[5]	X	X[6]
Dose-Response Evaluation	O	O	O	X[7]	O	X[7]
Risk Characterization	X[7]	X[8]	X[7]	X[7]	O	X[7]
RISK MANAGEMENT	X	X	X	X	O	X

[1] X = Significant effort.
O = Secondary effort (rely primarily on other agencies such as the Office of Environmental Health Hazard Assessment, Department of Health Services, Department of Fish and Game and the U.S. Environmental Protection Agency).

[2] Division of Water Quality, SWRCB.

[3] Division of Clean Water Programs, SWRCB.

[4] Human health hazards associated with Underground Storage Tanks (UST), landfills and other programs.

[5] Water quality monitoring including toxicity testing.

[6] Site monitoring and modeling (UST, landfills and land discharge programs).

[7] Chemical or site specific ambient water quality objective development.

[8] On a site specific basis.

ATTACHMENT 2

SWRCB'S STRATEGIC PLAN

GOAL

Our goal is to provide water resources protection, enhancement and restoration while balancing economic and environmental impacts.

STRATEGY

Ensure that water quality risk assessment practices are based on sound scientific knowledge, methods and practices; and are consistent internally and with U.S. Environmental Protection Agency and National Academy of Science to the extent appropriate.

PERFORMANCE MEASURES

1. Develop implementation plan for the RAAC recommendations as per Governor Wilson's Executive Order # W-137-96 (6/30/97)

2. Implement pertinent recommendations (1/1/99)

Attachment 3
SUMMARY OF STATE WATER RESOURCES CONTROL BOARD
DRAFT ACTION PLAN FOR IMPLEMENTATION OF THE SB 1082
RISK ASSESSMENT ADVISORY COMMITTEE RECOMMENDATIONS

ACTIVITY DESCRIPTION	PERFORMANCE MEASURES
I. Consistency and Harmonization	
• Establish internal Cal/EPA working group to insure agency-wide consistency and harmonization.	• Participate in Cal/EPA RAAC Policy Group. • Participate in Cal/EPA Risk Assessment Coordination Work Group. • Participate in Cal/EPA Environmental Fate and Transport Work Group. • Participate in Cal/EPA's Biological Technical Advisory Group.
• Initiate steps to assure consistency/ cooperation with USEPA and other federal counterparts.	• Participate in USEPA and Cal/EPA Risk Harmonization Work Group. • Policy meeting with USEPA to use USEPA standards for ambient and health risk criteria (ISWP/EBEP).
II. Best Use of Scientific Information and Development of Guidelines	
• Review data collection/management for overlap, institute quality control measures, and improve accessibility of present data.	• Develop proposal for Comprehensive Water Quality Data Management for collection, validation, dissemination. • Continue the SWRCB Information Management Team efforts to improve data accessibility.
• Clearly state the scientific and policy basis for each default option (e.g., cleanup to background levels).	• Participate in Cal/EPA development of guidance for communicating the basis for "science based" policy decisions.

SUMMARY OF STATE WATER RESOURCES CONTROL BOARD
DRAFT ACTION PLAN FOR IMPLEMENTATION OF THE SB 1082
RISK ASSESSMENT ADVISORY COMMITTEE RECOMMENDATIONS

ACTIVITY DESCRIPTION	PERFORMANCE MEASURES
III. Peer Review and Peer Involvement	
• Formalize peer review program.	• Continue SWRCB Science Advisory Committee.
IV. Interface between Risk Assessment and Risk Management	
• Seek early input from risk managers, external stakeholders and general public during risk assessment process.	• Continue external stakeholder involvement through existing and ad-hoc committees (e.g., surface water NPS/ISWP/EBEP/BPTCP, and disposal to land - Chapter 15 stakeholders groups).
• Better translation of emerging risk assessment methods into risk management policy.	• Identify SWRCB program areas that would benefit from this translation (e.g., underground tanks policy and ambient water quality standard program).
V. Organization and Resources	
• Balance level of effort and resources with the importance of the risk assessment.	• Incorporate economic/technical feasibility in ground water assessment. • Continue using a tiered approach for characterizing nature and extent of groundwater pollution.
• Evaluate adequacy of resources for various scientific disciplines required for risk assessment.	• Prepare (as appropriate) BCPs for in-house expertise in contaminant fate and transport, environmental chemistry, and modeling.
• Formalize staff participation in continuing education programs/ national and international scientific organizations.	• Continue existing Strategic Plan's training program, encourage staff participation in scientific organizations (e.g., SETAC).

DRAFT
(for discussion purposes only)

DEPARTMENT OF PESTICIDE REGULATION (DPR) WORK PLAN FOR THE IMPLEMENTATION OF RECOMMENDATIONS OF THE RISK ASSESSMENT ADVISORY COMMITTEE (RAAC)

May 2, 1997

I. Harmonization and Consistency

A. Utilize the DPR-U.S. EPA harmonization process to reduce duplication of effort.

1. Expand the harmonization process to include areas in addition to toxicology and exposure study review and human health risk assessment.
    a. Coordinate regulatory actions.
    b. Integrate environmental fate reviews into the harmonization process.

2. Increase the exchange of reviews and sharing of work products and workload to avoid duplication of effort.
    a. Track the number of work sharing instances used for registration decisions.
    b. Develop a quality assurance system to be implemented if the work sharing becomes a frequent procedure.

3. Work cooperatively with the U.S. EPA in implementing the Food Quality Protection Act.
    a. DPR assistance to U.S. EPA in meeting time frames.
    b. DPR representation on FQPA implementation panels.

4. Continued DPR participation, with U.S. EPA, on national and international harmonization work groups.
    a. Track the number of harmonization work groups in which DPR participates.

B. Continued participation within Cal/EPA to achieve consistency of risk assessment methods.

1. Continued participation in the Risk Assessment Coordination Work Group.

2. Continued participation in the Environmental Fate and Transport Work Group.

3. Finalize the cooperative project between OEHHA and DPR on organizational roles and responsibilities.

II. Peer Review

A. Develop a consistent DPR institutional peer review process.

1. Identify the types of DPR documents that are appropriate for internal or external peer review.

2. Identify different levels and types of review that are currently used by DPR. Identify additional means of providing peer review (internal and external).

3. The level of peer review should be commensurate with the document being reviewed.

4. Develop a set of Standard Operating Procedures for peer review.

III. Best Use of Scientific Information and Development of Guidelines.

A. Implement a program to encourage and support staff training and professional development.

1. Develop a DPR policy that facilitates participation of staff in continuing education and scientific societies, based on institutional needs and Individual Development Plans.

2. Encourage and support staff participation in state and national

scientific forums and publication of scientific papers on work related topics.

B. Document the procedures and assumptions used for scientific analyses.

1. Update scientific guidance documents. Include a documentation of the procedures as well as an identification of the default options and assumptions.

a. Medical Toxicology Branch guidance document on the conduct of risk assessments.

b. Worker Health and Safety Branch guidance document on the conduct of exposure assessments.

2. Document the characterization of uncertainty in the risk characterization process and ensure that the level of uncertainty is adequately and appropriately presented.

a. Medical Toxicology Branch.

b. Worker Health and Safety Branch.

3. Develop a procedure to regularly examine and update the risk assessment process and guidance documents.

a. Medical Toxicology and Worker Health and Safety Branches will meet on a regular basis to specifically make recommendations for changes.

C. Institute a process to ensure that the data collected and generated by DPR are in usable formats and are used in departmental analyses.

1. Catalog the data bases that are collected and maintained by DPR.

2. Implement a program to ensure that the data bases are in formats that are amenable to use in the appropriate programs.

3. Implement procedures to ensure that the appropriate data bases are fully utilized in departmental scientific analyses.

D. Institute a process to facilitate the incorporation of new scientific knowledge and technology.

1. Institute a seminar series for external scientists to present advances in science and technology.

2. Establish an interdisciplinary technical team to develop recommendations for the incorporation of new technological developments into the appropriate DPR procedures.

IV. Interface Between Risk Assessment and Risk Management

A. Institute a process to ensure that the risk assessments meet the needs of the DPR risk managers.

1. Implement a series of meetings between the risk managers and risk assessors to document the risk management needs.

2. Develop a process to ensure early consultation with risk managers in a risk assessment.

3. Finalize the process for external stakeholder scientific input into a risk assessment.

V. Organization and Resources

A. Optimize the operational efficiency and consistency of the risk assessment process.

1. Evaluate the risk assessment process and identify appropriate methods of increasing the efficiency of the process, while still maintaining scientific quality.

a. Task each branch to address those portions of the risk assessment process in the branch's area of responsibility.

2. Evaluate the DPR resource requirements with regards to risk assessment.

VI. Continual Improvement

A. Consider additional RAAC recommendations.

1. Update the implementation work plan on a yearly basis to incorporate additional RAAC recommendations.

DRAFT
(for discussion purposes only)

NARRATIVE DESCRIPTION OF THE DEPARTMENT OF PESTICIDE REGULATION WORK PLAN FOR THE IMPLEMENTATION OF RECOMMENDATIONS OF THE RISK ASSESSMENT ADVISORY COMMITTEE (RAAC)

May 2, 1997

Harmonization and Consistency

Utilize the DPR-U.S. EPA harmonization process to reduce duplication of effort

The Department of Pesticide Regulation (DPR) has a memorandum of understanding (MOU) with the Office of Pesticide Programs (OPP) of the U.S. Environmental Protection Agency (U.S. EPA). A major focus of the MOU is the harmonization of review and evaluation procedures. A major goal of the harmonization effort is to reach a level of consistency that will permit and promote sharing of resources and decrease duplication of effort. A primary focus of the harmonization effort has been on the review of toxicology and exposure studies as well as human health risk assessments. DPR will work with U.S. EPA to expand the project to include environmental fate and effects.

DPR will work to develop a closer coordination of regulatory activities. If DPR evaluates a chemical that OPP does not plan to evaluate for several years, a joint review becomes difficult. However, if both agencies plan regulatory action on or evaluation of a specific chemical in the same time frame, the sharing of resources for addressing that chemical will be helped.

DPR and OPP have shared study evaluations both to compare the conclusions of each agency and to utilize each other's evaluations. The comparison of conclusions leads to a harmonization of evaluation and assessment procedures. This, in turn, establishes a basis for using the evaluations of the other agency in place of a *de novo* evaluation. The initial exchanges have focussed on acute toxicity studies; however, the exchange of reviews of chronic toxicity studies is increasing. It is important to remain focussed on the fact that the goal is not the exchange of reviews for comparison alone, but the sharing of work to reduce duplication of effort. DPR will work to increase the number of instances in which work is shared in the process of reaching regulatory decisions. As the sharing of work products becomes more frequent, DPR will develop a quality assurance system for the evaluations conducted by OPP and used by DPR in its regulatory decisions.

The federal Food Quality Protection Act (FQPA), passed in 1996, contains many new requirements for U.S. EPA. DPR is currently working with OPP to identify various areas in which the DPR can provide assistance in meeting the requirements and time frames. DPR is currently exploring the possibility of doing evaluations for Section 18 Emergency Exemptions from Registration and in setting time-limited tolerances for these exemptions. In addition, DPR personnel serve on advisory panels for the implementation of the FQPA, such as the Working Group on Common Mechanism of Toxicity and Organophosphate Pesticides, and participate in the meetings of other work groups, such as the Endocrine Disrupter Screening and Testing Advisory Committee. OPP and DPR are working to increase such DPR representation.

Besides the above work groups, DPR is also working to increase its participation in international technical groups. DPR will continue to provide comments, through U.S. EPA, on relevant draft OECD guidelines. Department scientists are participating in the North America Free Trade Agreement (NAFTA) Technical Working Group on Pesticides: Occupational/Bystander/Residential. The goal of this working group is to harmonize the default assumptions and data analyses for worker and residential exposure assessments. Draft position papers have been prepared on several topics including protection factors for personal protective equipment and standard reference values.

DPR, U.S. EPA, and Health Canada are participating in a work share project for the review of data for a new active ingredient. In the current work share project, Canada will provide reviews of data related to exposure, reentry, and residue chemistry; U.S. EPA will provide reviews related to product and residue chemistry; and DPR will provide toxicology reviews. The three agencies will determine the adequacy of the shared data and will arrange a joint peer review process. Depending on the results of the current work share project, this cooperative process could be a model for future efforts.

<u>Continue to participate within Cal/EPA to achieve consistency of risk assessment methods.</u>

The RAAC recommended that Cal/EPA form an internal technical advisory group to ensure agency-wide consistency. The Standards and Criteria Work Group served this purpose on a more informal basis. In response to the RAAC recommendation, the Risk Assessment Coordination Work Group (RACWG) was formally

established under the lead of OEHHA. DPR is committed to participate in the efforts of the RACWG and has assigned resources, in the form of personnel, to the efforts. Also, in response to a recommendation of the RAAC, the RACWG formed the Environmental Fate and Transport Work Group. DPR is participating in this work group and in the initial efforts to catalog the various fate and transport models in use within Cal/EPA.

DPR and OEHHA are currently working to develop an agreement on the roles and responsibilities related to the evaluation of pesticides. The purposes of this agreement will be to eliminate duplication of effort, streamline the interagency review process, and share technical expertise.

Peer Review

Develop a consistent DPR institutional peer review process.

DPR recognizes the importance of peer review (internal and external) to ensure the high quality of its scientific documents. At the same time, DPR also recognizes the importance of ensuring that the level of review is commensurate with the importance of the document being reviewed and that the peer review process does not prevent the fulfillment of its statutory mandates. While DPR currently uses peer review, it does not have a consistent approach. DPR will develop a consistent institutional peer review process. The first step will be to identify the various types of documents produced by DPR for which technical review is appropriate. DPR will then identify the types and levels of review that are currently being used and will identify additional peer review procedures (internal and external) that could be used. DPR will develop a set of Standard Operating Procedures for a consistent and systematic approach to the peer review of DPR scientific documents.

Best Use of Scientific Information and Development of Guidelines

Implement a program to encourage and support staff training and professional development.

DPR recognizes the need to employ high quality science in its risk assessment activities. A highly trained technical staff, conversant with the latest scientific

information, is critical to meeting this need. At the same time, the DPR recognizes the need to remain focussed on the mission of the Department and to work within budgetary constraints. DPR will evaluate its existing procedures and develop or modify a professional development policy that will facilitate the participation of staff in continuing education. The continuing education may by sponsored by DPR or Cal/EPA or may occur through scientific societies. The continuing education will be based on the Individual Development Plans of staff as well as on the Departments institutional needs. Participation in scientific societies and state and national forums also play important roles in professional development. The publication of scientific papers in peer reviewed journals is also a means of receiving external input, remaining current on scientific issues, and promoting the activities of the Department. Therefore, the professional development policy will also specifically address participation in scientific forums and publication of scientific papers on work related topics and will address the pursuit of additional financial support.

Document the procedures and assumptions used for scientific analyses.

Written guidelines can be used to promote consistency, transparency, and quality in the scientific analyses conducted by the Department. DPR has used guidance documents for specific phases of the risk assessment process. These guidance documents will be expanded, updated, and completed. Special attention will be paid to both documenting procedures as well as identifying default assumptions and options. The guidance documents will also address uncertainty to ensure that uncertainty is adequately and appropriately presented in each risk assessment. The first efforts will be focussed on completing a Medical Toxicology Branch guidance document on the conduct of risk assessments and updating the Worker Health and Safety guidance document on the conduct of exposure assessments. A process will be instituted to regularly examine and update the risk assessment process and the guidance documents. The Medical Toxicology and Worker Health and Safety Branches will meet on a regular basis specifically to make recommendations for such changes.

Institute a process to ensure that the data collected and generated by DPR are in usable formats and are used in departmental analyses.

A large amount of data is collected and generated by DPR. In many cases, these data are assembled into data bases. However, there is no procedure to ensure that

these data bases are meeting the needs for which they were initially intended, are in useable formats for both internal and external use, and are utilized to their fullest extent in departmental analyses. DPR will initiate a process to catalog all the data bases developed and maintained by DPR. DPR will then implement a program to transform the data bases, as needed, into consistent formats that are amenable to use in the appropriate program applications. DPR will also implement procedures to ensure that scientific analyses, including risk assessments, fully use these data bases. We expect that this will be an ongoing and iterative process.

Institute a process to incorporate new scientific knowledge and technology.

There is sometimes a tendency for government agencies to become insular in their scientific activities, which can impede the incorporation of new scientific knowledge and technology. To help combat this tendency, DPR will institute a seminar series in which external scientists will present advances in science and technology. DPR will also establish an interdisciplinary technical team that will develop recommendations for the incorporation of new technological developments into the appropriate DPR procedures.

Interface Between Risk Assessment and Risk Management

Institute a process to ensure that the risk assessments meet the needs of DPR risk managers.

The RAAC concentrated on risk assessment issues; however, the review could not be totally divorced from risk management concerns. The value of a risk assessment will be judged based on its utility in enabling and supporting a sound risk management decision. While it is important to maintain a distinction between risk assessment and risk management, it is equally important to foster close communication and cooperation between the risk assessor and risk manager. The RAAC recognized this need and made several recommendations addressing communication and cooperation.

The Department will initiate a series of meetings between its risk assessors and risk managers. These meetings will not address specific chemicals, risk assessments, or risk management decisions, but will concentrate on the overall structure of the risk assessment process within DPR. The purpose of this interchange will be to

document the needs of the risk managers and to decide if the risk assessments meet these needs. Potential changes to the risk assessment and risk management processes may be identified. A process will be developed to ensure early consultation with risk managers on a risk assessment. The purpose of this consultation will be to give the risk assessor as much relevant information as possible (e.g., actual use practices for the application of the pesticide in question, probable exposure durations, identification of exposed populations, etc.).

A process is under development to facilitate early external shareholder scientific input into a risk assessment. As envisioned, a notice will be prepared that announces the initiation of a risk assessment, identifies the toxicology studies that are expected to be of primary importance in the risk assessment, identifies the toxicological values and endpoints (e.g., NOELs) that are expected to drive the risk assessment, and identifies some of the initial exposure values (e.g., dermal exposure) that may be used. The notices will also invite any additional relevant scientific data. DPR is currently evaluating procedures with which to release drafts of the risk characterization documents for comment. Some procedures may be initiated on a trial basis.

Organization and Resources

Optimize the operational efficiency and consistency of the risk assessment process.

Increasing pressures on available resources and expanding departmental risk assessment needs demand that the risk assessment process be as efficient as possible, while not sacrificing scientific quality. The most appropriate means for increasing the efficiency can best be identified by the people performing the risk assessments, with appropriate information from the risk managers regarding their needs. Each DPR branch that contributes to the risk assessment process will address those portions of the risk assessment process in the branch's areas of responsibility and will identify various ways to increase efficiency, while still maintaining the appropriate level of scientific quality. This process will also identify the resource needs regarding risk assessment. This is expected to be an iterative process.

Continual Improvement

DPR recognizes that this initial work plan primarily addresses the major areas of RAAC recommendations. DPR will revisit and update this work plan on a yearly basis. Such modifications may also identify the need for changes to the Department's strategic plan.

DRAFT FOR DISCUSSION ONLY

Air Resources Board FINAL DRAFT Action Plan for Implementation of the SB 1082 RAAC Recommendations May 8, 1997

In October 1996, the Risk Assessment Advisory Committee (RAAC) released its report entitled A Review of the California Environmental Protection Agency's Risk Assessment Practices, Policies, and Guidelines. In this report, the RAAC describes its findings and recommendations for improvements to the California Environmental Protection Agency's (Cal/EPA) risk assessment activities. In December 1996, Governor Pete Wilson signed Executive Order W-137-96 which, in part, requires the Boards, Departments and Offices of Cal/EPA to evaluate the report and develop plans to implement the Committee's recommendations. This is the Air Resources Board's (ARB) plan to implement the RAAC's recommendations.

Peer Review:

Recommendation:

- Evaluate peer review practices for scientific peer review

On-going Activities:

- AB 1807 Toxic Air Contaminant Identification (TAC) Program
  - Hold public workshop(s)
  - Public comment periods
  - Scientific Review Panel reviews and makes recommendations
- TAC and Indoor Exposure Research Projects
  - Research Screening Committee reviews proposed research projects and Final Reports from funded projects
  - External peer review obtained on some projects as needed

Future Activities:

- Continue to peer review the AB 2588 Air Toxics "Hot Spot" Integrated Software through a subgroup of the California Air Pollution Control Officers Association's (CAPCOA) Toxics Committee
- Incorporate by reference the Office of Environmental Health Hazard Assessment's (OEHHA) Risk Assessment Guidelines into the "Hot Spots" Emission Inventory Criteria and Guidelines Report
  - Hold public workshops
  - Public review and comment period
  - Board approval

DRAFT FOR DISCUSSION ONLY

Interface Between Risk Assessment and Risk Management:

Recommendations:

- Early input from public, stakeholders, and risk managers
- Improve communication between risk assessors and risk managers
- Risk assessors translate emerging methods to risk managers

On-going Activities:

- Internal meetings and public workshops
- Continue to get early input from local, state and federal agencies, public, and stakeholders
- Participate in Toxics Committee of the CAPCOA (meetings every second month)
- AB 1807 TAC Identification Process
  - Hold public workshop(s)
  - Public comment periods
  - Scientific Review Panel reviews and makes recommendations
- SB 1731 Risk Reduction Audits and Plans (began 1/93; expected completion 12/97)
- Participate in United States Environmental Protection Agency's (U.S. EPA) development of the Urban Area Source Program
- Participate in U.S. EPA's Residual Risk Working Group
- Review and comment on District Toxic New Source Review Rules

Future Activities:

- Incorporate approved Cal/EPA Risk Characterization Policy into risk assessments
- Develop risk management guidelines for inorganic lead in cooperation with the Office of Environmental Health Hazard Assessment
- Update Risk Management Guidelines for New and Modified Sources
- Incorporate OEHHA Risk Assessment Guidelines into the "Hot Spots" Emission Inventory Criteria and Guidelines Report

Exposure Assessment:

Recommendations:

- More emphasis on receptor-based exposure assessment when appropriate and cost-effective
- Integrate fate and transport modeling efforts with human exposure assessment
- Improve characterization of uncertainty and variability
- Establish a cross-cutting external advisory group to identify issues and problems best addressed with a receptor-based exposure assessment approach

On-going Activities:

- Validate California Population Indoor Exposure Model (target completion date 2001)

- Fund research on source apportionment and exposure assessment, indoor air chemistry, pollutant delivery, and personal exposure

- Examine ways to apportion human exposures to TAC sources
- Work with the U.S. EPA to expedite approval of new outdoor air exposure models
- Continue to fund research to refine assumptions for fate and transport such as the current research efforts designed to study ozone and particulate matter in the San Joaquin Valley and South Coast Air Basins
- Provide uncertainty and variability measures in exposure estimates
- Participate in cross-cutting external advisory group on receptor-based exposure assessments
- Participate in Risk Assessment Advisory Committee Work Group with other Cal/EPA Boards and Departments
- Coordinate with Department of Toxic Substances Control on risk assessments which evaluate air impacts of hazardous waste
- Update the AB 2588 "Hot Spots" Emission Inventory (ATEDS) with more accurate and current emissions data
- Distribute the California Air Toxics Emission Factor (CATEF) database to enable more accurate estimation of air toxics emissions
- Merge air toxics emission inventory data with the criteria pollutant emission inventory database
- Continue to update stationary source test methods to provide more accurate and precise emissions data for risk assessment and emissions inventory

Future Activities:

- Develop an integrated indoor and outdoor exposure model (reasonable target date 2005)
- Seek additional funds to expand personal exposure and source apportionment research efforts
- Pursue additional funds for research on improved ways to estimate and present uncertainty and variability in exposure estimates
- Periodically re-evaluate the needs of the monitoring network to determine the adequacy of the data being collected
- Update the California Air Toxics Emission Factor (CATEF) database with new emission factors and more user-friendly software
- Make available air toxics emission estimation information and tools via the ARB's World Wide Web pages

Consistency With U.S. EPA:

Recommendation:

- Initiate steps to assure consistency and cooperation with federal counterpart

Completed Activities:

- Continue to work closely with U.S. EPA to integrate California data into U.S. EPA's Exposure Factors Handbook (revised every 5 years)

On-going Activities:

- Follow U.S. EPA Exposure Assessment Guidelines provided in the Federal Register dated May 29, 1992, and adhere to their definitions for Indoor Air Program
- Follow U.S. EPA, Scientific Advisory Board (SAB), and National Academy of Sciences (NAS) guidance for estimating human exposure
- Participate in Fate and Transport Work group
- The Toxics Air Monitoring Database is being added to the U.S. EPA Aerometric Information Retrieval System (AIRS)
- Participate in U.S. EPA's Residual Risk Working Group
- Participate in development activities for U.S. EPA's Urban Area Source Program

Future Activities:

- Coordinate with U.S. EPA on future exposure assessments under the AB 1807 program

Continuing Education:

Recommendations:

- Continuing education for staff on risk assessment, new models, new science, etc.
- Public Education

On-going Activities:

- Encourage staff attendance at meetings, seminars, scientific meetings, and training courses
- Continue to develop informational material for the public
- Continue to publish indoor air quality guidelines that tell the public how they can reduce their exposures to pollutants
- Establish AB 2588 "Hot Spots" Page on the World Wide Web to provide information and tools necessary to complete accurate air toxics emission inventories and risk assessments

Future Activities:

- Periodically reassess training needs
- Provide air toxics emissions data and facility risk information on the AB 2588 "Hot Spots" Web Page

Databases:

Recommendation:

- Review data collection and management to minimize overlap and improve accessibility

On-going Activities:

- Currently developing ways of providing monitoring data to public and government agencies through Internet and compact discs (expected completion date 10/97)
- Continue to provide indoor exposure data from research contracts on diskettes, through the National Technical Information System (NTIS), etc.

- Currently re-evaluating the needs of the monitoring network to determine the adequacy of the data being collected
- The Toxics Air Monitoring Database is being added to the U.S. EPA Aerometric Information Retrieval System (AIRS)
- Update the AB 2588 Air Toxics Emission Data System (ATEDS) with more current and accurate data
- Revise the structure of the AB 2588 Fee Regulation database to enable data sharing and comparisons with ATEDS data
- Work with OEHHA to restructure their AB 2588 Risk Assessment database to enable data sharing and comparisons with ARB AB 2588 databases

Future Activities:

- Periodically re-evaluate the needs of the monitoring network to determine the adequacy of the data being collected
- Update the California Air Toxics Emission Factor (CATEF) database with new emission factors
- Merge AB 2588 air toxics emissions data (ATEDS) with ARB criteria pollutant emissions database (CEIDARS)
- Make available air toxics emission data and risk assessment result data from the ARB World Wide Web pages

ARB/SSD/SES
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May 8, 1997

Integrated Waste Management Board (IWMB), Cal/EPA

Integrated Waste Management Board (IWMB) participated in the statewide Risk Assessment Advisory Committee meetings. The department reviewed the report of the committee and has determined that those areas covered by the report and Executive Order W-137-96 represent a negligible portion of our overall mandates. For that reason, IWMB will not be including any elements associated with assessment of toxicity, exposure to, or risk of chemicals in the environment to human health in the Board's Strategic Plan. On matters related to human health risk assessment, IWMB will consult with Office of Environmental Health Hazard Assessment (OEHHA) or other state agencies.

IWMB will, however, continue to participate in the Risk Assessment Coordination Work Group (RACWG) meetings and any other RACWG activities which may have an impact on Board programs.

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY

RISK ASSESSMENT COORDINATION WORK GROUP

The Risk Assessment Coordination Work Group (RACWG) is a working group composed of scientists representing State programs that are involved in human health and ecological risk assessments. The RACWG acts as an advisory group on scientific issues for the California Environmental Protection Agency (Cal/EPA), with primary emphasis on toxicology and risk assessment. Meetings of the RACWG provide a forum for the discussion of scientific issues having broad-based application among different programs.

The composition, mandate, and functions of the RACWG are consistent with a recommendation -- made by the Risk Assessment Advisory Committee convened pursuant to Senate Bill 1082 (Chapter 418, Statutes of 1993)[1] -- for an internal Cal/EPA working group specifically charged with ensuring agency-wide consistency and harmonization.

Mission Statement:

The Risk Assessment Coordination Work Group provides advice on toxicology and human health and ecological risk assessment issues to the executive officers and directors of boards and departments within Cal/EPA, and to the Secretary for Environmental Protection. Through its activities, the RACWG aims to ensure that risk assessments which are used as the basis for risk management decisions reflect the best available science, and that the risk assessments employ practices and methods that are consistent throughout the Agency. To the extent appropriate, the RACWG will also attempt to harmonize Cal/EPA's risk assessment practices with those of the U.S. Environmental Protection Agency.

The RACWG strives to achieve consensus among Cal/EPA scientists on issues relating to toxicology and risk assessment. By providing an opportunity for scientists to meet, identify, discuss, debate and coordinate scientific issues and activities, the RACWG seeks to ensure that science policy decisions and risk assessment criteria, guidance and policies used for regulatory decision-making are based on a firm foundation of science.

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[1] A Review of the California Environmental Protection Agency's Risk Assessment Practices, Policies, and Guidelines: Report of the Risk Assessment Advisory Committee. (October, 1996)

Structure:

The RACWG is composed of scientists representing the following boards and departments in Cal/EPA:

- Office of Environmental Health Hazard Assessment
- Department of Toxic Substances Control
- Department of Pesticide Regulation
- Air Resources Board
- State Water Resources Control Board/Regional Water Quality Control Boards
- California Integrated Waste Management Board

Non-Cal/EPA departments that have a role in human health and ecological risk assessments may participate in RACWG activities as non-voting members.

The Office of Environmental Health Hazard Assessment will chair the meetings of the RACWG until April 1997, at which time the RACWG will consider whether there should be a rotation of the chair among the boards and departments.

Mechanism for Reaching Decisions:

The RACWG will discuss issues brought before it for resolution, and attempt to reach consensus. Consensus building may require the RACWG to engage in a vigorous debate during which differing viewpoints will be presented and argued.

A strong preference is to have decisions arrived at through consensus. If at the end of the debate, however, consensus cannot be reached, RACWG members will cast votes for the viewpoint which they feel should go forward as the group's decision. Each of the member boards and departments is allotted one vote, to be cast by a designated board/departmental representative. Member boards and departments are expected to vote only on issues in which they have interest or expertise. Prior to the meeting at which an issue is to be discussed, departmental representatives are urged to determine what the consensus view is among scientists within their respective departments on the issue in question.

In instances when consensus cannot be achieved, and voting is necessary, the RACWG will prepare an issue memo providing background information on the subject in question, discussing the various viewpoints expressed during the debate, and presenting the different options available for addressing the issue. The RACWG will submit the issue memo to the directors and executive officers for further policy guidance or dispute resolution. Unresolved disputes concerning strictly scientific issues will be assigned for further study by a subcommittee of the RACWG.

Risk Assessment Coordination Work Group
Environmental Fate & Transport Subcommittee

The Environmental Fate & Transport Subcommittee was initiated in response to a direct recommendation of the Risk Assessment Advisory Committee. The Subcommittee is being lead by Dr. Jeff Wong of DTSC, and is composed of technical experts from DTSC, DHS, RWQCB, OEHHA, DPR, ARB and SWRCB. The purpose of the Subcommittee is to develop an inventory of expertise, practices and resources across all Cal/EPA and to provide a forum to exchange information and improve consistency in the application of environmental fate and transport approaches and models. Initially, the Subcommittee will prepare an inventory of modeling capabilities, experts, resources, and established guidance across all Cal/EPA organizations. The Subcommittee noted the need for more inter- and intra-organization interactions and coordination, and also the need to consider seminar or other readily available training opportunities to facilitate the understanding of model structure, assumptions and appropriate applications. The Subcommittee is scheduled to meet once per quarter.

RISK CHARACTERIZATION POLICY: GUIDANCE FOR IMPLEMENTATION

This document was prepared by the Risk Assessment Coordination Work Group (RACWG) of the California Environmental Protection Agency (Cal/EPA) to provide guidelines for the boards and departments within the Agency to apply in characterizing risks from exposures to chemicals in the environment. While it is the intent of the RACWG, in developing these guidelines, to establish consistency in the manner by which risks are characterized within Cal/EPA, the RACWG also recognizes that statutory or regulatory constraints may require a board or department to deviate from certain aspects of the policy.

BACKGROUND

The Risk Assessment Advisory Committee (RAAC), convened pursuant to Senate Bill 1082 (Chapter 418, Statutes of 1993), recently completed a comprehensive review of the Cal/EPA risk assessment policies, methods and guidelines. In the area of risk characterization, the RAAC[1] specifically recommended that:

- Cal/EPA should improve the characterization of uncertainty and variability in its risk assessments and in the communication of this information to risk managers and the public; and,

- The extent and depth of Cal/EPA risk assessments should be responsive to the needs of the decision-maker and to the decisions they are intended to support.

[1] *A Review of the California Environmental Protection Agency's Risk Assessment Practices, Policies, and Guidelines.* Report of the Risk Assessment Advisory Committee, page ES-3. October 1996.

IMPLEMENTATION OF THE RAAC'S RECOMMENDATIONS

With regard to guidance documents relating to risk characterization, the RAAC recommended that "(T)o improve the current structure of its risk characterization, Cal/EPA should develop guidelines by building on the U.S. EPA March 1995 *Policy for Risk Characterization*..."

The U.S. EPA policy, along with the accompanying *Guidance for Risk Characterization*, establishes a framework of values, principles and elements designed to ensure that a full characterization of risk -- including an evaluation of the confidence and uncertainties in the risk assessment -- is clearly and effectively presented.

Pursuant to the RAAC's recommendations, Cal/EPA has adopted the U.S. EPA *Policy for Risk Characterization* as the **interim** policy governing the preparation of risk characterizations at Cal/EPA. In adopting the U.S. EPA policy as interim, Cal/EPA recognizes that modifications will likely be necessary to better meet the needs of the boards or departments, or to reflect new scientific knowledge.

GUIDANCE FOR IMPLEMENTATION

The National Research Council's *Science and Judgment in Risk Assessment* (NRC, 1994) defines risk characterization as follows: "Risk characterization involves integration of information from the first three steps (of the risk assessment process) to develop a qualitative or quantitative estimate of the likelihood that any of the hazards associated with the agent of concern will be realized in exposed people. This is the step in which risk assessment results are expressed. Risk characterization should also include a full discussion of the uncertainties associated with the estimates of risk."

The U.S. EPA policy emphasizes the need for clarity, comparability and consistency in risk characterizations. It also calls for a full characterization of risk -- i.e., addressing qualitative and quantitative features of the assessment, and identifying the important strengths and uncertainties as part of a discussion of the confidence in the assessment.

The guidelines in this document will ensure that the day-to-day risk assessment and risk management practices of the Cal/EPA boards and departments apply the principles and reflect the values set forth in the interim policy. The major concepts presented in the U.S. EPA *Policy for Risk Characterization* and its accompanying documents are highlighted below (in italicized text), followed by steps by which these concepts can be incorporated into Cal/EPA activities. In developing these guidelines, consideration was given to the specific observations and recommendations of the RAAC relating to risk characterization.

Overall Implementation:

The RAAC recommended that Cal/EPA take steps to improve the knowledge and understanding of uncertainty and its implications among both technical staff and policy makers (Ibid., page 7-5). Cal/EPA recognizes that its ability to effectively control risks resulting from exposures to hazardous chemicals can be significantly enhanced by ensuring that risk managers and risk assessors have a good understanding of both risk management and risk assessment processes. A training course on the principles of risk assessment, the process by which the products of risk assessments are considered along with other relevant factors in arriving at risk management decisions, and approaches for effectively communicating the results of risk assessments and risk management decision-making to the public will be adopted. Cal/EPA staff who have a role in either risk assessment or risk management should be strongly encouraged to attend this course. The course will be updated as needed to reflect changes in risk management or risk assessment approaches.

In addition, the boards and departments should continually assess the training needs of their technical and policy-making staff. The breadth and depth of the Agency-wide training course will be evaluated periodically, in light of input provided by the boards and departments based upon their assessment of staff training needs.

Key Aspects of Risk Characterization:

1. *<u>Bridging risk assessment and risk management</u> -- Risk characterizations should be clearly presented, and separate from any risk management considerations; risk management options should be developed using the risk characterization and should be based on consideration of all relevant factors, scientific and nonscientific.*

   a) Risk assessors and risk managers should be sensitive to distinctions between risk assessment and risk management.

   More specifically, the U.S. EPA risk characterization policy describes the following roles for generators of the assessments (risk assessors) and for users of the assessment/decision-makers (risk managers):

   "For the generators of the assessment, distinguishing between risk assessment and risk management means that scientific information is selected, evaluated, and presented without considering issues such as cost, feasibility, or how the scientific analysis might influence the regulatory or site-specific decision. Assessors are charged with (1) generating a credible, objective, realistic, and scientifically balanced analysis; (2) presenting information on hazard, dose-response, exposure and risk; (3) explaining confidence in each assessment by clearly delineating strengths, uncertainties and assumptions, along with the impacts of these factors (e.g., confidence limits, use of conservative/non-conservative assumptions) on the overall assessment. They do not make decisions on the acceptability of any risk level for protecting public health or selecting procedures for reducing risks.

   "For users of the assessment and for decision-makers who integrate these assessments into regulatory or site-specific decisions, the distinction between risk assessment and risk management means refraining from influencing the risk description through consideration of other factors -- e.g., the regulatory outcome -- and from attempting to shape the risk assessment to avoid statutory constraints, meet regulatory objectives, or serve political purposes."

Each board and department should define the role(s) of their respective programs in risk assessment or in risk management, and provide this information to staff. This will assist staff in understanding their roles as individual risk assessors or risk managers, and enable them to be cognizant of the need to maintain the separation between risk assessment and risk management considerations.

In any document that incorporates the results of both the scientific assessment and the regulatory decision-making process, there should be a clear distinction between the scientific conclusions and the policy judgments.

b) Risk characterization is only one of several kinds of information used for regulatory decision-making.

It is recommended that each board and department identify the statutory, regulatory and policy considerations that may affect the risk management decision, and how these are taken into account in the decision-making process.

2. <u>*Discussing confidence and uncertainties*</u> *-- Key scientific concepts, data and methods should be discussed, along with a statement of confidence in the assessment identifying all major uncertainties and their influence on the risk assessment.*

a) The risk characterization integrates the information from the hazard identification, dose-response and exposure assessments, using a combination of qualitative information, quantitative information, and information regarding uncertainties.

An outline (similar to U.S. EPA's *Conceptual Guide for Developing Chemical-Specific Risk Characterizations*) of the qualitative and quantitative information to be included in the risk characterization, discussing the relevant information considered and analyses conducted, in each step of the risk assessment process will be developed for Agency-wide use. This outline can provide a basic framework which may be modified as necessary to suit the needs of a specific program.

In response to a recommendation by the RAAC, the outline can include information on the consequences of exposures greater than the safe exposure level. A discussion of the risk assessor's confidence in these conclusions should also be included.

Each board and department may customize this outline so as to highlight statutory, regulatory or policy constraints that require the use of specified data, models, or default assumptions.

A separate outline, intended to assist staff in the boards and departments in presenting the results of a risk assessment to the public, will also be developed. This outline will be designed to guide the boards and departments in ensuring that the public is provided with comprehensive and comprehensible information on the scientific data and considerations that entered into the risk assessment, including a discussion of the risk assessor's confidence in the assessment, and areas of uncertainty.

b) The risk characterization includes a discussion of uncertainty and variability.

The discussion of uncertainty should address the sources of the uncertainty (e.g., measurement errors, data gaps), and a discussion of how the data, models or assumptions used in the assessment impacted the conclusions about risk. Where statutes, regulations, or policies (including guidance documents) specify the use of certain data, models or assumptions to address uncertainty, these should be clearly identified in the risk characterization.

U.S. EPA suggests that the discussion of uncertainty and variability reflect the type and complexity of the risk assessment. The RAAC recommended that the Agency improve the characterization of uncertainty and variability in its risk assessments and in communicating this information to risk managers and the public. To respond to both the U.S. EPA and the RAAC recommendations, an Agency-wide effort to develop more specific guidelines for addressing uncertainty and variability may be useful. These guidelines could include criteria for determining the nature and extent of the uncertainty and variability discussions that would be appropriate given the type and complexity of a risk assessment. This effort could include a review of the types of assessments

conducted by or for each board and department, in order to provide information that may be useful in setting expectations regarding the degree to which uncertainty and variability should be addressed. Such guidelines could be incorporated as part of the outlines discussed under Item #2(a).

c) Well-balanced risk characterizations present risk conclusions and information regarding the strengths and limitations of the assessment for other risk assessors, decision-makers and the public.

In presenting the results of the risk assessment, the risk assessor should make an effort to include a discussion of his/her confidence in the assessment, and of the qualitative and quantitative factors that affect the overall assessment of hazard and risk, particularly as these pertain to the conclusions that may be of special interest to the risk manager and interested or affected parties. The outlines suggested under Item #2(a) should provide for inclusion of this information.

3. *Presenting several types of risk information -- Information should be presented on the range of exposures derived from exposure scenarios and on the use of multiple risk descriptors; risk managers should use risk information appropriate to their program legislation.*

The Agency will establish procedures designed to ensure that any information available (or accessible) to risk managers which may be relevant in the risk assessment (e.g., regarding the characteristics of the population in question -- or subgroups within that population) is effectively relayed to the risk assessors for consideration in the risk assessment. Assumptions made regarding the distribution of susceptibilities to hazards should be explicitly described.

Prior to the commencement of a risk assessment, risk managers and risk assessors should discuss the purpose of the risk assessment and any specific information and risk descriptors that may be of particular interest in regulatory decision-making, including:

a) individual exposure and risk descriptors (e.g., high end estimates, central tendency

estimates);

b) population risk descriptors (e.g. probabilistic number of cases, estimated percentage of population with risk greater than a given level);

c) descriptors of the distribution of risk among subpopulations (e.g., highly exposed subgroup, highly susceptible subgroup); and,

d) situation-specific risk information (corresponding to future events, or regulatory options).

Such discussions would be useful in ensuring that the risk assessment is responsive to the needs of the decision-maker and the decisions they are intended to support.

A discussion of the uncertainty associated with any of the descriptors presented should be included in the presentation of the information.

Risk characterization principles

A document entitled *Elements to Consider When Drafting EPA Risk Characterizations* accompanies the U.S. EPA policy. Since the concepts reflected in these principles are already incorporated in the options presented for implementing the ***Key Aspects of Risk Characterization*** above, no further guidelines are offered, and the principles are simply listed below:

- *Risk assessments should be transparent, in that the conclusions drawn from the science are identified separately from policy judgments, and the use of default values or methods and the use of assumptions in the risk assessment are clearly articulated.* [See Item #1(a).]

- *Risk characterizations should include a summary of the key issues and conclusions of each of the other components of the risk assessment, as well as describe the likelihood of harm. The summary should include a description of the overall strengths and the limitations (including uncertainties) of the assessment and conclusions.* [See Item #2(a),(b),(c).]

- *Risk characterizations should be consistent in general format, but recognize the unique characteristics of each specific situation.* [See Item #2(a).]

- *Risk characterizations should include, at least in a qualitative sense, a discussion of how a specific risk and its context compares with other **similar** risk estimates. This may be accomplished by comparisons with other chemicals or situations in which the Agency has decided to act, or with other situations with which the public may be familiar. The discussion should highlight the limitations of such comparisons.* [Cal/EPA will consider whether this is appropriate for its assessments; some concern regarding the use of comparisons with exposures to other chemicals or with other situations was expressed by certain members of the Risk Assessment Coordination Work Group.]

- *Risk characterization is a key component of risk communication, which is an interactive process involving exchange of information and expert opinion among individuals, groups and institutions.* [See Item #3.]

APPENDIX:
Memorandum from Carol M. Browner, Administrator, U.S. Environmental Protection Agency, re: USEPA Risk Characterization Program, dated March 21, 1995